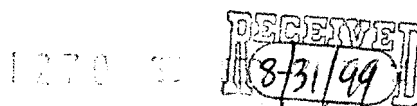




Shaklee Corporation

Shaklee Terraces
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Telephone 415/954-3000



August 24, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation notifies FDA that it has begun using the following statements:

- For hormonal balance during menopause
- PhytoFem contains 80 mg of the well-researched herb black cohosh that helps regulate hormonal balance in women during the transitional period of menopause.
- Ease the transition to menopause.
- Nutritional support for hormonal balance during menopause.
- PhytoFem has been formulated to provide the following key ingredients for hormonal balance during menopause in amounts based on independent clinical studies and published research (black cohosh, soy isoflavones, flaxseed, dong quai, red clover and licorice).
- Black cohosh contains compounds that appear to act on the hypothalamus and vasomotor centers of the brain, areas that help regulate body functions such as temperature control, sleep patterns and a sense of emotional well-being. Complex chemicals in black cohosh are believed to suppress the secretion of luteinizing hormone, which fluctuates during menopause.
- Soy is currently being studied for its benefits during menopause, for bone, heart and breast health, and for maintaining healthy cholesterol levels.

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- Flaxseed, also known as linseed, is the richest whole grain source of a class of phytoestrogens called lignans. Like soy isoflavones, these lignans are structurally similar to human estrogen and can bind to estrogen receptors on the surface of many cells of the body, thereby exerting an estrogen-like effect.
- Dong quai--traditionally used with other herbs as a uterine tonic.
- A plant that grows throughout the United States, Europe and Northern Asia, the blossoms of red clover contain phytoestrogens similar to those found in soy. The isoflavones formononetin, biochanin A and daidzein and genistein are present and have been found to exert estrogen-like activity.
- A daily serving of PhytoFem supplies 30 mg of isoflavones (genistein, daidzein and glycitein) compounds currently the subject of scientific research for their role in the many health benefits associated with soy. Taken along with a serving of Energizing Soy Protein, one easily reaches the level of isoflavones showing promise in supporting hormonal balance during menopause.
- Scientific studies suggest that along with a healthy diet and lifestyle, consuming phytoestrogens (plant estrogens) may compensate for some of the reduced production of hormones during menopause. Phytoestrogens occur in significant amounts in black cohosh, soy and flaxseed and are remarkably similar in molecular structure to the female hormone estrogen. They are thought to exert estrogen-like activity in the body, helping to regulate the normal hormone fluctuation that occurs during menopause.
- PhytoFem also provides phytoestrogens from dong quai, red clover and licorice. The combination of these actions appear to be beneficial, . . .

which contain the statutory statement, on labels and in labeling the following product:

PhytoFem" Dietary Supplement

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,



Christopher Jensen, Ph.D.
Director, Health Sciences